

REMARKS

I. Claim Amendments

Claim 1 is canceled and Claims 2-3 are amended in this Response. All the Claims, including the amendments, are shown in the previous section. No new matter has been added. Specifically, Claim 2 is amended to include "sheep." Support for this amendment can be found at page 3, lines 4-5 of the Specification. Further, Claims 2 and 3 are amended to more particularly define the selenium concentration of the composition. Support for this amendment can be found at page 4, lines 23-25 of Applicants' Specification and Claim 1 as originally filed.

Upon entry of this amendment, Claims 2-5 will be pending in the Application.

II. Rejection Under 35 U.S.C. §112, First Paragraph

Claims 3-5 stand rejected under 35 U.S.C. §112, first paragraph, because the Specification, while being enabling for the treatment of poor hair growth or alopecia, allegedly does not reasonably provide enablement for the prevention of poor hair growth or alopecia. Applicants have traversed the rejection for the reasons set forth below. In particular, Applicants have amended the Claims to require "at least assisting in" the prevention of poor hair growth or alopecia.

The purpose of the enablement requirement is "to ensure that the invention is communicated to the interested public in a meaningful way." MPEP §2164. To that end, the disclosure of an application must be sufficient to inform those skilled in the relevant art how to make and use the invention. *Id.* "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *U.S. v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988).

In the instant Application, Applicants clearly articulate both how to make and use the treatment of Claim 3, including how to use the treatment to at least assist in preventing poor hair growth or alopecia. For example, at page 2, lines 22-30, Applicants specifically set forth the means for determining the quantity of selenium to be used in the treatment. Applicants also clearly state that the selenium can be administered in an animal's diet or through specific supplements to be fed to the animal. See, e.g., page 2, line 35 to page 3, line 2. Accordingly, it

is submitted that one skilled in the art could make or use the invention from the disclosures in the Specification coupled with information known in the art such that undue experimentation is not necessary. Thus, Applicants respectfully submit that amended Claim 3 is sufficiently enabled such that the rejection under 35 U.S.C. §112, first paragraph, has been traversed.

Claims 4 and 5, which depend in whole or in part from Claim 3, are submitted to be enabled under 35 U.S.C. §112, first paragraph, for at least the reasons set forth with respect to Claim 3. Reconsideration and withdrawal of the rejection is requested.

III. Rejections Under 35 U.S.C. §102

1. Rejection under 35 U.S.C. §102(a) or §102(e)

Applicants have canceled Claim 1, thus mooting the rejection under 35 U.S.C. §102(a) or §102(e) as being anticipated by Shields, Jr. *et al.* (U.S. Patent No. 6,156,355) or Hayek *et al.* (U.S. Patent No. 6,238,708).

2. Rejection under 35 U.S.C. §102(b)

Claims 1, 3, and 4 stand rejected under 35 U.S.C. §102(b) as being anticipated by McDonald. Applicants have canceled Claim 1, thus mooting the rejection as to that Claim. As to Claims 3 and 4, Applicants have traversed the rejection for at least the reasons set forth below. Specifically, the above reference cannot support a finding of anticipation because not every element in amended Claims 3 and 4 is found in McDonald.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131.

McDonald does not anticipate each and every element set forth in Claim 3. McDonald reports a trial in which 0.1 mg selenium per kg body weight was given orally to ewes and/or lambs at three month intervals. *See* page 433. Amended Claim 3 requires the administration to dogs, cats or sheep of from about 0.5 to 4.5 mg of selenium per kg of diet on a dry matter basis. Because McDonald does not teach the administration of 0.5 to 4.5 mg selenium per kg of diet on a dry matter basis, the reference does not anticipate each and every element of

Claim 3. Thus, Claim 3 is patentable over the cited reference under 35 U.S.C. §102(b). Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 4, which depends from Claim 3, is submitted as patentable over the cited reference for at least the same reasons set forth with respect to Claim 3.

IV. Rejection Under 35 U.S.C. §103

Claims 1-5 stand rejected under 35 U.S.C. §103(a) as being obvious over WO 98/11122, Lee *et al.*, Shields, Jr. *et al.*, Hayek *et al.*, Arthur *et al.*, Ahsan *et al.*, and Messenger. Applicants have canceled Claim 1, thus mooting the rejection as to that Claim. As to Claims 2-5, Applicants have traversed the rejection for the reasons set forth below.

Claims 2-5 are patentable over the combination of WO 98/11122, Lee *et al.*, Shields, Jr. *et al.*, Hayek *et al.*, Arthur *et al.*, Ahsan *et al.*, and Messenger because the Office has failed to establish a *prima facie* case of obviousness. Applicants submit that there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings to support a *prima facie* case of obviousness. Thus, WO 98/11122, Lee *et al.*, Shields, Jr. *et al.*, Hayek *et al.*, Arthur *et al.*, Ahsan *et al.*, and Messenger cannot be taken together to teach or suggest a method for controlling the rate of hair growth in a dog, cat, or sheep comprising feeding the animal about 0.5 to about 4.5 mg selenium per kg of diet on a dry matter basis. Applicants also submit that the cited references cannot be taken together to teach or suggest that dietary regulation of selenium will prove critical to at least assist in preventing or treating poor hair growth or alopecia.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. In addition, the references when combined must teach or suggest all the claim limitations. See MPEP §2143. Further, obviousness must be reviewed from the perspective of one skilled in the art at the time of the invention without the benefit of hindsight. *Tyco Indus. v. Tiny Love, Ltd.*, 914 F. Supp. 1068, 1079 (D.N.J. 1996). The combination of two or more references is "hindsight" where "express" motivation is lacking. See MPEP §2145. Thus, there must be a teaching or suggestion within the prior art, or within the general knowledge of a person of

ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor. *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 USPQ 1321, 1329 (Fed. Cir. 1998). Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. *Id.*

In the instant Application, Claim 2 is directed to a method for controlling the rate of hair growth and Claim 3 is directed to a method for at least assisting in preventing or treating poor hair growth in a dog, cat, or sheep. The methods each comprise feeding the dog, cat, or sheep a hair growth rate controlling amount of selenium of from about 0.5 to about 4.5 selenium mg/kg of diet on a dry matter basis. Applicants submit that any reasoning focused on the application of specific selenium amounts with the benefit of hair growth, as required for Claim 2, or treatment or prevention of alopecia, as required for Claim 3, to formulate an obviousness rejection is an application of impermissible hindsight. Nothing in the cited references offers a sufficient motivation to combine reference teachings, and even if combined, the cited references fail to teach each of the claim limitations, thus a *prima facie* case of obviousness cannot be established.

WO 98/11122 reports nutritional supplements including 0.01 mg to 5 mg selenium. While the reference indicates that low levels of selenium have been associated with an increased risk of hair abnormalities, the reference does not include hair growth in its list of health benefits associated with increased daily selenium intake. Thus, the reference does not teach or suggest all of the claim limitations. Further, as discussed in detail below, there is no motivation to combine the teachings of WO 98/11122 with other references to arrive at the present invention.

Lee *et al.* state the dietary requirement for sheep and cattle as 0.1 to 0.3 mg selenium/kg dry matter. *See, Lee et al.* at 1344. The reference does not teach or suggest an amount of selenium greater than 0.3 mg selenium/kg dry matter to be administered in the diet of an animal for the purposes of controlling the rate of hair growth or at least assisting in preventing or treating poor hair growth or alopecia in animals. In fact, Lee *et al.* teach away from any combination with the selenium range of WO 98/11122 in that the reference reports a

range of 0.1 mg to 0.3 mg selenium/ kg dry matter which comprises the low end of the range of WO 98/11122, and which is further entirely outside of the claimed range. Thus, the cited reference does not provide any suggestion or motivation to combine the reference with the other references, and actually teaches away from any potential combination.

Shields, Jr. *et al.* report a dog food formulation for working dog breeds analyzed to contain a minimum of 0.4 mg/kg selenium. *See* column 20, lines 31-47. However, the reference does not disclose a range of selenium values beyond the 0.4 mg/kg value. Further, Shields, Jr. *et al.* do not teach or suggest incorporation of selenium into a formulation for the purposes of controlling the rate of hair growth or at least assisting in preventing or treating poor hair growth or alopecia in animals. Shields, Jr. *et al.* report the incorporation of selenium only for the purpose of benefiting cardiomyopathies of different species. *See* column 9, lines 53-61. The reference does not teach any value within the range discussed in Lee *et al.* Moreover, just as in Lee *et al.*, the lower value of Shields Jr. *et al.* teaches away from the higher range reported in WO 98/11122. Thus, there is no suggestion or motivation in Shields, Jr. *et al.* to combine the reference with the other references to achieve either the method as required for Claim 2 or the method as required for Claim 3.

Hayek *et al.* report a pet food composition comprising 0.27 mg of selenium per kg of dry matter in the mineral mix. *See, e.g.*, column 19, line 17. As with the Shields Jr. *et al.*, nothing in the reference remotely teaches or suggests that selenium amounts in general are critical to controlling the rate of hair growth or critical to preventing or treating poor hair growth or alopecia. Hayek *et al.* reports a value distinct from the 0.4 mg/kg selenium value of Shields Jr. *et al.* Moreover, while the reference teaches a value within the range discussed in Lee *et al.*, the lower value of Hayek *et al.* teaches away from that reported by WO 98/11122. Thus, there is no suggestion or motivation in Hayek *et al.* to combine the reference with the other references.

The remaining three cited references relate to alternative research studies involving selenium targets and effects performed on rats or human skin cells. For example, Arthur *et al.* state the possibility that selenium deficiency may cause abnormal plasma thyroid hormone concentrations by inhibiting the synthesis and activity of the iodothyronine deiodinases in rats. Ahsan *et al.* report on the immunohistochemical localization of thyroid hormone

receptors in human scalp skin cells in vitro. Messenger discusses the regulatory nature of thyroid hormone and its expression in the human hair follicle.

Nothing in the cited references teach or suggest a method of controlling the rate of hair growth, as required by Claim 2, or at least assisting in preventing or treating poor hair growth or alopecia in animals, as required by Claim 3. Also, unlike any of the references discussed above, the references fail to teach or suggest any specified amount of selenium for administration to an animal, including a dog, cat, or sheep to control hair growth. Thus, there is no suggestion or motivation to modify or combine these three references with each other or with the other references.

In sum, Applicants submit that there is no suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings to support a *prima facie* case of obviousness. Thus, Claim 2 and Claim 3 are not obvious under 35 U.S.C. §103(a) over any combination of 98/11122, Lee *et al.*, Shields, Jr. *et al.*, Hayek *et al.*, Arthur *et al.*, Ahsan *et al.*, and Messenger.

Because no *prima facie* case of obviousness may be established for independent Claim 3, it is respectfully submitted that a *prima facie* case of obviousness cannot be established for Claims 4 and 5, which depend from independent Claim 3. Reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) is requested.

V. Conclusion

In summary, the Claims have been amended and the rejections under 35 U.S.C. §102, §103(a), and §112 have been obviated or overcome. In view of the foregoing Remarks, it is submitted that the Claims are in condition for allowance. Reconsideration of the Application as amended is requested and allowance of the Claims at an early date is solicited.

If the Examiner believes that personal communication will expedite prosecution of this Application, the Examiner is invited to call the undersigned at the number listed below.

Respectfully submitted,



Wendell Ray Guffey

Reg. No. 31,762

Phone: 785-286-8285

Email: ray_guffey@hillspet.com

Hill's Pet Nutrition, Inc.
Capitol Tower Building
400 SW 8th Avenue
Topeka, Kansas 66603

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Wendell Ray Guffey